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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 331,375	12 03 1999	CHARLES M. COHEN	CIBT-P01-519	1578

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BOSTON, MA 02110-2624

EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 12/20/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09 331,375

Examiner

Regina M. DeBerry

Applicant(s)

COHEN ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be obtained under the provisions of 37 CFR 1.136(a) only if requested no later than the last date for filing a reply.
- 3 MONTH(S) from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, and if within the statutory period of thirty (30) days a reply is filed, the period for reply specified above shall be extended to thirty (30) days.
- Failure to reply within the set or extended period of time will constitute abandonment of the application under 37 CFR 1.131(b).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may be taken into account for patent term adjustment. See 37 CFR 1.714(b).

Status

- 1) ☐ Responsive to communication(s) filed on 15 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 21-23, 25-27 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-20, 24, 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-648)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other _____

Status of Application, Amendments and/or Claims

The amendment filed 15 October 2002 (Paper No. 16) has been entered in full. Claims 1, 5-20, 24, 28 and 29 are under examination.

Priority under 35 USC 371 and 35 U.S.C. 119(e) have been referenced.

Applicant maintains that an abstract was submitted (page 8, 15 October 2002, Paper No. 16). However, it appears that the abstract has been separated from the file. Applicant is requested to submit a copy of the abstract with the next response.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The objection to the disclosure (Brief Description of Figures) as set forth at page 4 of the previous Office Action (08 May 2002, Paper No. 13) is *withdrawn* in view of the amendment (15 October 2002, Paper No. 16).

The rejections of claims 1, 5, 8-10, 15, 16, 20, 24, 28, and 29 under 35 U.S.C. 102(b) as anticipated by Field, WO 95/14079 (IDS, AA, Paper No. 11) as set forth at pages 4-5 of the previous Office Action (08 May 2002, Paper No. 13) is *withdrawn* in view of the amendment (15 October 2002, Paper No. 16).

The rejections of claims 6, 7, 11, 12, 12, 14, 17-19 under 35 U.S.C. 103(a) as anticipated by Field, WO 95/14079 (IDS, AA, Paper No. 11) in view of Cohen *et al.* WO 92/15323 as set forth at pages 6-8 of the previous Office Action (08 May 2002, Paper No. 13) is *withdrawn* in view of the amendment (15 October 2002, Paper No. 16).

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-20, 24, 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are generally drawn to a method comprising implanting myogenic precursor cells into a mammal and treating the myogenic precursor cells with a morphogen sufficient to promote proliferation or differentiation into functional myocardium and a therapeutic composition comprising myogenic precursor cells and an amount of morphogen sufficient to promote proliferation or differentiation of said cells into a functional myocardium.

The specification teaches the isolation of the OP-1 morphogen. The subject matter sought to be patented as defined by the claims is not supported by an enabling disclosure. The specification does not teach how to implant a preparation of myogenic precursor cells into a mammal and treat said myogenic precursor cells with an amount of a morphogen sufficient to promote proliferation or differentiation of said myogenic precursor cells into functional myocardium. The specification does teach the proliferation or differentiation of myogenic precursor cells into myocardium after morphogen treatment. The specification does not teach the potential effects or

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morphogens on any kind of cells in any kind of biological activities. The specification does not teach isolating myogenic precursor cells and culturing said cells with a morphogen to produce proliferation or differentiation of said myogenic precursor cells into a functional myocardium.

The specification fails to provide any evidence that myogenic precursor cells have differentiated into functional myocardium. The specification fails to disclose that assays were employed to discern heart muscles (functional myocardium) versus skeletal muscles. The specification does not teach therapeutic compositions for promoting the repair or regeneration of mammalian myocardium. The specification does not teach that a skeletal progenitor cell can switch fate after being in contact with morphogen and become a heart muscle cell useful for repairing heart tissues. There are no assays that teach how morphogens can be used to treat damaged myocardium. Furthermore, it is unclear how to treat myogenic precursor cells with a morphogen *subsequent* to implanting said preparation of myogenic precursor cells into said mammal.

The specification states that it has not been shown that treatment of myogenic precursor cells with morphogens is useful in promoting the proliferation and/or differentiation of myogenic precursor cells into new and functional myocardium in a morphogenically permissive environment or that morphogenically-treated myogenic precursor cells are useful in the treatment of lost or damaged mammalian myocardium (page 5, lines 3-10). In addition, the specification fails to disclose any examples

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demonstrating enablement of the recited claims. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth.

Due to the large quantity of experimentation necessary to demonstrate implanting myogenic precursor cells into a mammal and treating said myogenic precursor cells with an amount of a morphogen sufficient to promote proliferation or differentiation of said myogenic precursor cells into functional myocardium, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention and the contradictory state of the prior art, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Conclusion

No claims are allowed.

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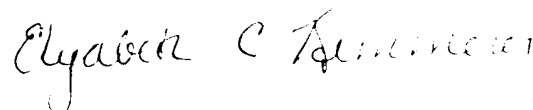
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



RMD
December 17, 2002



ELIZABETH C. HAMMER
FEB 14 2003